

AWARD NUMBER: W81XWH-14-2-0165

TITLE: GWOT Vascular Injury Study 2 Supplemental Project:
Impact of Prophylactic Fasciotomy

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13. SUPPLEMENTARY NOTES					
14. ABSTRACT This study will involve a retrospective analysis of large patient cohort of US service members included in the GWOTVII database as having sustained wartime LEVI with and without fasciotomy in the wars in Afghanistan and Iraq. The GWOTVII database will be used to initially identify patients, and will then be used to provide demographic information and data on injury characteristics, complications, other injures, and limb salvage information. Information regarding fasciotomy wound management and iatrogenic complications of fasciotomy will be obtained from individual patient records. Information specific for return-to-duty and long-term disability will be obtained from the Physical Evaluation Board Liaison Office. for each branch of service.					
15. SUBJECT TERMS Vascular Injury, Compartment Syndrome, Extremity, Fasciotomy					
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Table of Contents

	<u>Page</u>
1. Introduction	2
2. Keywords	2
3. Accomplishments	2
4. Impact	3
5. Changes/Problems	3
6. Products	3
7. Participants & Other Collaborating Organizations	4
8. Special Reporting Requirements	4
9. Appendices	5

1. INTRODUCTION:

This is a retrospective analysis of a cohort of US service members included in the wartime vascular injury database. Information regarding service members with a lower extremity vascular injury will be used to determine fasciotomy rates, wound management, and iatrogenic complications. The impact of injury and fasciotomy on the service members' return-to-duty and long-term disability will also be examined.

2. KEYWORDS:

Vascular Injury
Compartment Syndrome
Extremity
Fasciotomy

3. ACCOMPLISHMENTS:

- IRB protocol has been approved by MRMC IRB (5 June 2015)
- HRPO has approved the protocol (5 June 2015)
- Approval to obtain initial cohort of patients for study (27 July 2015)
- Data Sharing Agreement with Defense Health Agency (DHA) for access to medical records approved (28 August 2015)
- One time patient population/data received from Wartime Vascular Injury Initiative (11 September 2015)
- Review of charts/patient records began (15 September 2015)
- Plan to hire additional staff to review charts (January 2016)

What were the major goals of the project?

The overall goal is to determine the impact of the widespread use of fasciotomies on current medical/surgical practices, management guidelines, medical needs, as well as future research direction. The specific aims are:

- Aim 1. Characterization of patients-demographics, injury, fasciotomy.
- Aim 2. Characterize the morbidities associated with fasciotomy.
- Aim 3. Determine the impact of fasciotomy on delayed amputation rate.
- Aim 4. Characterize fasciotomy wound management.

What was accomplished under these goals?

Major activities were focused on preparing for data collection and chart reviews. All regulatory, human subject and IRB approvals were obtained to begin the project. There was a significant delay (January - August 2015) in obtaining all the regulatory approvals necessary to begin chart reviews and data collection. Once all approvals were received, a cohort of 860 patients with lower extremity vascular injuries and attempted limb salvage was obtained and integrated into a database. A Data Sharing Agreement (DSA) to access Defense Health Agency (DHA) systems was approved (28 August 2015) and chart reviews began mid-September.

What opportunities for training and professional development has the project provided?

Nothing to report

How were the results disseminated to communities of interest?

Nothing to report

What do you plan to do during the next reporting period to accomplish the goals?

During the next reporting period chart reviews will continue. Additional staff will be hired to assist with chart reviews.

4. IMPACT:

As the project is just beginning chart reviews to obtain data, there has not been enough data collected to change practice or behaviors.

What was the impact on other disciplines?

Nothing to report

What was the impact on technology transfer?

Nothing to report

What was the impact on society beyond science and technology?

Nothing to report

5. CHANGES/PROBLEMS:

Nothing to report

Changes in approach and reasons for change

Nothing to report

Actual or anticipated problems or delays and actions or plans to resolve them

Nothing to report

Changes that had a significant impact on expenditures

Nothing to report

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents

Nothing to report

6. PRODUCTS:

Nothing to report

Publications, conference papers, and presentations

Nothing to report

Journal publications

Nothing to report

Books or other non-periodical, one-time publications

Nothing to report

Other publications, conference papers, and presentations

Nothing to report

Website(s) or other Internet site(s)

Nothing to report

Technologies or techniques

Nothing to report

Inventions, patent applications, and/or licenses

Nothing to report

Other Products

Database to collect data was developed.

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Name:	Thomas Walters, PhD
Project Role:	PI
Nearest person month worked:	3
Contribution to Project:	Dr. Walters is the PI of the award
Name:	Diane Miller
Project Role:	Program Manager
Nearest person month worked:	12
Contribution to Project:	Budgetary and administrative management of the award
Name:	Julie Cutright
Project Role:	Research Nurse
Nearest person month worked:	3
Contribution to Project:	Data abstraction, data management

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?

Nothing to Report

What other organizations were involved as partners?

Organization Name: United States Institute of Surgical Research
Location of Organization: 3698 Chambers Pass
JBSA Fort Sam Houston, TX 78234

Partner's contribution to the project

- Facilities – Project staff use the partner's facilities for project activities
- Collaboration – Partner's staff work with project staff on the project
- In-kind support – Partner makes software, computers, equipment, etc. available to project staff

8. SPECIAL REPORTING REQUIREMENTS

QUAD CHARTS: See attached

9. APPENDICES:

Quad Chart

GWOT Vascular Injury Study 2 Supplemental Project: Impact of Prophylactic Fasciotomy

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PI: Thomas J. Walters, Ph.D.

Org: USAISR/The Geneva Foundation

Award Amount: \$791,101

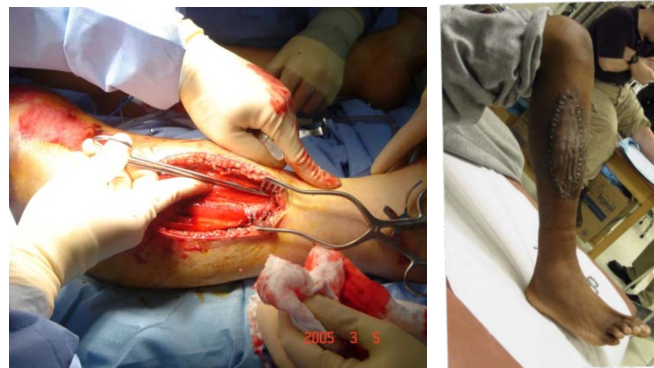


Study/Product Aim(s)

- Specific Aim 1: Identify patients that received fasciotomies and characterize the data relating to demographics, mortality, primary injury, complications, return-to-duty, long-term disabilities.
- Specific Aim 2: Determine the incidence of morbidities associated with fasciotomy; 3) assess the impact of fasciotomy on delayed amputation; and 4) characterize fasciotomy wound management.

Approach

This study will involve a retrospective analysis of a cohort of US service members included in the GWOTVII database. Information regarding fasciotomy wound management and iatrogenic complications of fasciotomy will be obtained from individual patient records. Information specific for return-to-duty and long-term disability will be obtained from the Physical Evaluation Board Liaison Office for each branch of service.



(Left) Fasciotomy of the anterior compartment of the lower leg. (Right) The need to close fasciotomy wound with skin graft suggests that muscle swelling was sufficient to induce compartment syndrome. This project will examine the complications and morbidities associated with fasciotomy wounds.

Timeline and Cost

Activities	Year 01	Year 02
Obtain IRB/HRPO approval, Hire Staff and FaVIO database development	<div><div></div></div>	
Extract data from GWOTVII database	<div><div></div></div>	
Conduct Chart Reviews	<div><div></div></div>	
Data Analysis and Reporting		<div><div></div></div>
Estimated Budget (\$791K)	\$339K	\$452K

Goals/Milestones

CY14 Goal – Protocol /Staffing

- ☒ Write and submit protocol to IRB
- ☒ Hire project manager

CY15 Goals – Data Collection

- ☒ Obtain IRB and HRPO approval
- ☐ Complete staff hiring
- ☒ Extract data
- ☒ Conduct chart reviews

CY16 Goals – Data Collection/Analysis

- ☐ Conduct chart reviews
- ☐ Analyze data
- ☐ Submit results for publication

Comments/Challenges/Issues/Concerns

- Currently only 2 staff reviewing charts. Plan to hire additional staff in CY 2016

Budget Expenditure to Date

Projected Expenditure:\$339K

Actual Expenditure: \$121,746

Updated: 1 October 2015